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Pesticide Fact Sheet Number 50: Pendimethalin

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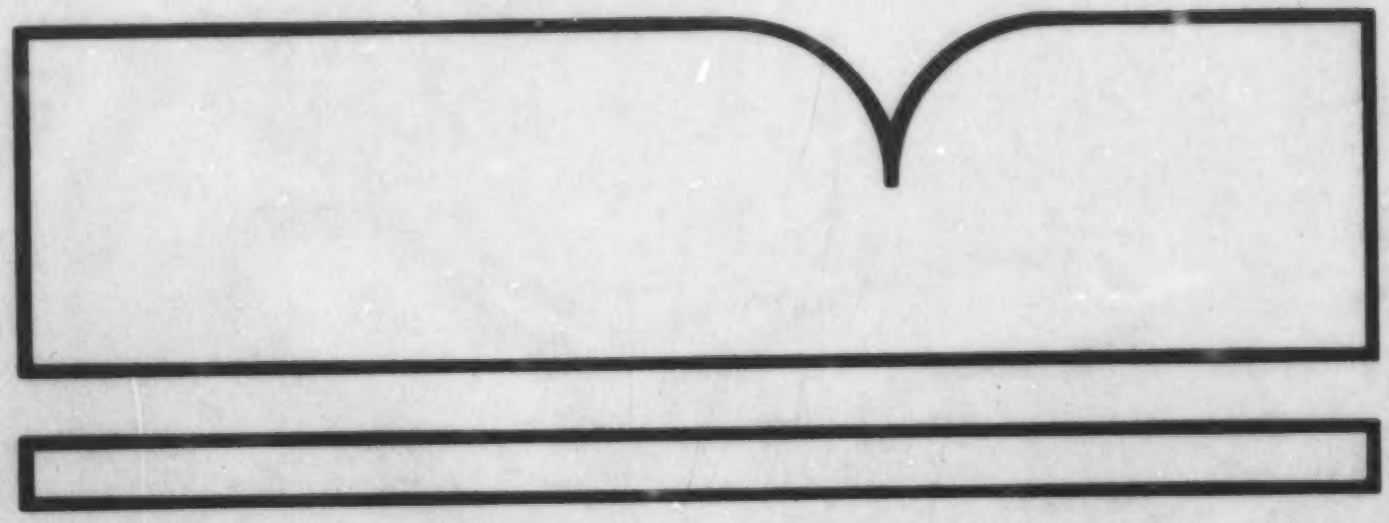

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EPA, Office of Pesticide Programs, Registration Division

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US Environmental Protection Agency
Office of Pesticide Programs
Registration Division, TS-767C
401 M Street, S.W.
Washington, D.C. 20460

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors
Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-768C)
Washington, DC 20460

EPA

Pesticide Fact Sheet

Name of Chemical: PENDIMETHALIN
Reason for Issuance:
Date Issued: March 31, 1985
Fact Sheet Number: 50

1. Description of the chemical:

Generic name: N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine
Empirical formula: $C_{13}H_{19}N_3O_4$
Common name: Pendimethalin
Trade name: Prowl®, Herbadox®, Stomp®, and AC 92553
Chemical Abstracts Service (CAS) Registry number: 40487-42-1
Office of Pesticides Program's EPA Chemical Code Number: 108501
Year of initial registration: 1974
Pesticide type: Herbicide
Chemical family: Dinitroaniline
U.S. producer: American Cyanamid Company

2. Use patterns and formulations:

Application sites: Pendimethalin is registered for control of broad leaf weeds and grassy weed species on the following sites: soybeans, cotton, field corn, beans, peanuts, potatoes, rice, sorghum, sunflower, tobacco, ornamentals, non-bearing fruit and nut crops, and vineyards.

One site, jojoba, is registered under Section 24(c) in Arizona.

Types of formulations: Pendimethalin is available in granular, dispersable granular, and emulsifiable concentrate formulations.

Types and methods of applications: Pendimethalin is mainly applied as a preplant incorporation (except in corn, rice and sorghum), preemergence spray, early postemergence (rice), and late postemergence "culti-spray" (field corn and sorghum) applications.

Application rates: 0.5 to 2.0 lbs a.i./A on crop sites.

Usual carriers: Attapulgite clay and water.

3. Science Findings:

Summary science statements:

Pendimethalin is not acutely toxic by the oral, dermal, inhalation and occular routes of exposure. The available data is insufficient to show that any of the risk criteria listed in § 162.11(a) of Title 40 of the U.S.Code of Federal Regulations have been met or exceeded for the uses of pendimethalin at the present time. There are no valid mutagenicity and chronic rat studies for pendimethalin and insufficient oncogenicity data. There are also extensive residue chemistry and environmental fate data gaps.

Pendimethalin is highly toxic to coldwater fish, highly to moderately toxic to warmwater fish and highly to moderately toxic to freshwater invertebrates. A detailed ecological hazard assessment cannot be made until certain environmental chemistry data requirements, and a monitoring study of aquatic sites next to treated rice fields are fulfilled.

Chemical characteristics:

Pendimethalin is crystalline at room temperature and has a fruit like odor. Its molecular weight is 281.30. The boiling point is 330°C. Pendimethalin is soluble in water (at 20°C) to <0.50 ppm and soluble in aromatic and chlorinated hydrocarbon solvents.

Toxicological characteristics:

Acute toxicology effects on pendimethalin are as follows:

Acute Oral Toxicity in rats: >1,250 mg/kg body weight, Toxicity Category III
Acute Dermal Toxicity in rabbits: >5,000 mg/kg body weight, Toxicity Category III
Acute Inhalation Toxicity in rats: >320 mg/l (4 hour exposure) Toxicity Category IV
Skin irritation in rabbits: slight irritant, Toxicity Category III
Eye irritation in rabbits: corneal irritation clearing in less than seven days, Toxicity Category III.

Subchronic toxicology data except for the 90-day rat feeding study have met the current toxicity requirements.

Chronic toxicology effects on pendimethalin have not been completely evaluated because there are no valid mutagenicity and chronic rat studies for pendimethalin, and insufficient oncogenicity data.

A 2-year dog feeding study indicated that pendimethalin tested at 12.5 mg/kg, 50.0 mg/kg and 200.0 mg/kg produced increases in alkaline phosphatase level and liver weight. The NOEL is 12.5 mg/kg/ day.

A teratology test in rats has shown that pendimethalin tested at 500.0 mg/kg, highest dose tested (HDT), failed to induce teratogenic, or fetotoxic effects. A teratology test in rabbits has shown that pendimethalin tested at 60.0 mg/kg (HDT), failed to induce teratogenic or fetotoxic effects.

A reproduction study (3-generation rat) indicated that pendimethalin tested at 500 ppm to 5,000 ppm induced slightly fewer offspring, with no corresponding increase in deaths and decreased weight gain from weaning to maturity. The NOEL is 500 ppm.

Major routes of human exposure:

Non-dietary exposure to pendimethalin by a farmer as an applicator during mixing, loading , spraying and flagging is probable.

Physiological and biochemical behavioral characteristics:

Absorption characteristics: Pendimethalin is absorbed in limited amounts by monocotyledonous plants and in moderate amounts by small dicotyledonous plants.
Translocation: Pendimethalin is taken up from the soil by plants in very limited amounts.
Mechanism of pesticidal action: Pendimethalin inhibits plant cell division and cell elongation.
Metabolism in plants: Pendimethalin is principally degraded in plants by oxidation of the 4-methyl group(benzene ring) and the N-1-ethylpropyl group in the amine moiety.

Environmental characteristics:

Adsorption and leaching in basic soil types: Pendimethalin is strongly adsorbed by soil organic matter and clay and does not readily leach through the soil.
Microbial breakdown: Soil microorganisms do not appear to play a significant role in degradation of pendimethalin.
Loss from photodecomposition and/or volatilization: Slight losses.
Average persistence at recommended rates: When used at recommended rates under normal environmental conditions, little if any pendimethalin occurs in the subsequent crop.

Ecological characteristics:

Avian acute oral toxicity: 1,421 mg/kg.
Avian eight-day dietary toxicity (Bobwhite Quail): > 3,149 ppm.
Avian eight-day dietary toxicity (Mallard Duck): > 4,640 ppm.
96-hour fish toxicity: 0.199 ppm for bluegill sunfish (highly toxic) and 0.138 ppm for rainbow trout (highly toxic).
48-hour aquatic invertebrate toxicity: 0.28 ppm (highly toxic for Daphnia magna.

Potential problem for endangered species:

The Slackwater darter and certain freshwater mussels are endangered species at risk from the use of pendimethalin on cotton. The Agency is addressing appropriate means of labeling pesticides that may threaten the continued existence of endangered species. The labeling should be completed by the 1986 growing season. If it is not, this standard may be amended to impose interim labeling to protect endangered species.

The Agency believes that the conventional labeling approach may be inadequate to properly inform the users on how to protect the endangered species. The Agency anticipates that appropriate labeling will be developed in time for the 1986 growing season for cotton.

Tolerance assessments:

The Agency is unable to complete a full tolerance reassessment of pendimethalin because of certain residue chemistry and toxicology data gaps. The additional data may cause specific tolerances to be revised in the future.

The Acceptable Daily Intake (ADI) for pendimethalin was originally based upon a 2-year feeding study on rats, which was subsequently declared invalid. Subsequently, the Provisional Acceptable Daily Intake (PADI) for pendimethalin was calculated, using the 90 day portion of the same study. The subchronic portion of this study was used instead of a 2-year dog study because the (P)ADI value calculated for the rat is the more conservative value on a mg/kg basis than for the dog:

	NOEL (mg/kg)	Safety Factor	(P)ADI mg/kg/day	(P)MPI mg/day (60 kg
Rat	25.0	2,000	0.0125	0.7500
Dog	12.0	100	0.1250	7.5000

The No-Observable-Effect-Level (NOEL) for the rat study is 25.0 mg/kg. A 2,000-fold safety factor was used and the PADI was calculated as 0.0125 mg/kg/day with a Maximum Permissible Intake (MPI) of 0.7500 mg/day for a 60 kg person. The Theoretical Maximum Residue Contribution (TMRC) for pendimethalin-based permanent tolerances is 0.0166 mg/day for a 1.5 kg diet. Currently, the permanent tolerances utilize 2.22 % of the PADI.

In the United States, tolerances are currently established in 40 CFR § 180.361 for the combined residues of the herbicide, pendimethalin: N-(1-ethyl propyl)-3,4-dimethyl-2,6-dinitrobenzenamine and its metabolite: 4-[1-ethyl propyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol, in or on the raw agricultural commodities listed below:

	Commodities	Parts per million
**	Beans (lima, dry, snap)	0.1
**	Beans, forage	0.1
**	Beans, hay	0.1
	Corn, fodder	0.1
	Corn, forage	0.1
**	Corn, fresh(including sweet, K+CWHR)	0.1
	Corn, grain	0.1
	Cottonseed	0.1
	Peanuts	0.1
	Peanut hay	0.1
	Peanut forage	0.1
	Rice grain	0.05
	Soybeans	0.1
	Soybeans, forage	0.1
	Soybeans, hay	0.1
	Sunflower seeds	0.1

** The tolerances for these commodities were established after the science reviews for the pendimethalin registration standard were completed.

International Tolerances

Presently, there are no tolerances for residues of pendimethalin in Canada, Mexico, or in the Codex Alimentarius.

Problems known to have occurred with use:

The Pesticide Incident Monitoring System (PIMS) indicates four incidents involving agricultural uses of pendimethalin alone from 1966 through 1980. Of the four incidents, three required medical attention, two involved dermal exposure during ground application, one involved mixer/ loader exposure and one involved a truck/ container spill. No fatalities were reported.

PIMS does not include any details or consequences of these exposures, nor does it attempt to validate these voluntarily submitted reports. The PIMS data do not provide information on chronic health effects from exposure to pendimethalin, but do support the need for precautions relating to careful handling of pendimethalin products.

4. Summary of regulatory position and rationale:

Based on the review and evaluation of all available data and other relevant information on pendimethalin the Agency has made the following determinations:

The available data do not indicate that any of the risk criteria listed in § 162.11(a) of Title 40 of the U.S.Code of Federal Regulations have been met or exceeded for the uses of pendimethalin at the present time.

Pendimethalin is not acutely toxic by the oral, dermal, inhalation and ocular routes of exposure.

The chronic dog study, rat and rabbit teratology studies, and a 3-generation reproduction study did not indicate adverse chronic effects.

- There are no valid mutagenicity and chronic rat studies for pendimethalin, and insufficient oncogenicity data. There are also extensive residue chemistry and environmental fate data gaps.

The Agency is requiring monitoring data for potential residues in aquatic sites next to treated rice fields. Once the Agency has evaluated these additional data, it will determine if EPA should impose more stringent measures to minimize exposure of aquatic organisms to pendimethalin. Ecological effect studies indicate that pendimethalin is highly toxic to certain coldwater and warmwater fish; moderately to highly toxic to marine and estuarine organisms.

The Agency is requiring that levels of N-nitroso-pendimethalin contaminant not exceed 60ppm in the technical product and that the technical be analysed for other impurities.

Specific label warning statement:

Hazard Information

The human hazard statements must appear on all EP labels as presribed in 40 CFR 162.10.

Environmental Hazard Statements

All manufacturing-use products (MPs) intended for formulation into end-use products (EPs) must bear the following statements:

"This pesticide is toxic to fish. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency".

End-Use Product Statements

a. Non Aquatic Uses (Granular products)

The following environmental hazard statement must appear on all EPs:

"This pesticide is toxic to fish. Do not apply directly to water. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. In case of spills, either collect for use or dispose of properly".

b. Non Aquatic Uses (Nongranular products)

The following environmental hazard statement must appear on all EPs:

"This pesticide is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes".

c. Aquatic Uses (Rice)

The following environmental hazard statement must appear on all EPs:

"This pesticide is toxic to fish and aquatic organisms. Fish may be killed at application rates recommended on the label. Do not contaminate water by cleaning of equipment or disposal of wastes".

"Do not apply to rice fields if fields are used for catfish or crayfish farming".

Restrictions on Rotational Crops

"Pending the submission of rotational crop data, do not apply pendimethalin on rice fields in which crayfish or catfish farming are included in the cultural practices, and do not plant crops in pendimethalin-treated fields unless pendimethalin is registered for use on those crops".

Restrictions on Irrigated Crops

"Pending the submission of irrigated crop data, do not use water containing pendimethalin residues from rice cultivation to irrigate food or feed crops which are not registered for use with pendimethalin".

5. Summary of major data gaps:

The following toxicological studies are required:
A dermal sensitization study in guinea pig is required by October 30, 1985,
A 90-day feeding study in the rat is required by January 30, 1986,
A chronic toxicity study in rat is required by April 30, 1989,
An oncogenicity study in rat and in mouse is required by April 30, 1989.
The following mutagenicity data are required by October 30, 1985:
a. Gene mutation in bacteria,
b. Gene mutation in mammalian cells in culture,
c. Chromosomal aberration analysis in mammalian cells in culture, and
d. DNA damage in mammalian cells in culture.

The following environmental fate data are required:
A photodegradation study in water is required by October 30, 1985,
A photodegradation study on soil is required by October 30, 1985,
A metabolism test in aerobic soil is required by April 30, 1987,
A metabolism test under anaerobic aquatic conditions is required by April 30, 1987,
A metabolism test under aerobic aquatic conditions is required by April 30, 1987,

A mobility study involving leaching and adsorption/desorption is required by October 30, 1985,
A mobility study involving volatility in the lab is required by October 30, 1985,
A mobility study involving volatility in the field is required by October 30, 1985,
A soil dissipation study in the field is required by April 30, 1987,
A dissipation study in aquatic (sediment) is required by April 30, 1987,
An accumulation study in rotational crops (confined) is required by October 30, 1987,
An accumulation study in rotational crops (field) is required by April 30, 1987,
An accumulation study in irrigated crops (field) is required by October 30, 1987,
An accumulation study in fish is required by October 30, 1985.

The following ecological effects data are required:

An acute freshwater invertebrate toxicity study using a typical EP is required by October 1985.
An aquatic field study to monitor residues next to rice fields using a typical EP is required by April 1987.

The following product chemistry data are required by October 30, 1985:
The name and address of the manufacturer or producer of each starting material used in the 90% technical product,
A discussion of each impurity believed to be present at >0.1% based on the beginning materials, all chemical reactions and any contamination is required by April 30, 1986,
Five or more samples must be analyzed for the active ingredient (A.I.) and each impurity present for which a certified limit is required by April 30, 1986,
A current Confidential Statement of Formula,
Quantitative methods to determine the remaining impurities in the technical product by April 30, 1986.
Data are required for ppm solubility in various solvents at 20 C,
Dissociation Constant data,
Octanol/water partition coefficient data,
Data on the pH, and
The following data are required for chemical stability: discussion of sensitivity of the A.I. to metal and metal ions, stability of the A.I. at normal and elevated temperatures, and the sensitivity of the A.I. to sunlight.

The following residue chemistry data are required:

Additional plant metabolism data are required with radiolabeled pendimethalin by April 30, 1987.

Levels of metabolites remaining unextractable in plant tissues and in polar fractions must be determined for possible toxicological residue concerns by April 30, 1987.

Metabolism studies utilizing ruminants dosed with ^{14}C ring labeled pendimethalin required by April 30, 1986. Distribution and characterization of residues must be determined in milk, muscle, kidney, and liver. If the ruminant metabolism differs significantly from the rat data, then swine metabolism data will also be required. If the additional metabolism data show the presence of new metabolites, then additional methodology data may be required.

Additional data are required by April 30, 1986 to show the stability of pendimethalin and its 3,5-dinitrobenzl alcohol metabolite in or on representative plant and animal samples stored at freezing temperatures.

Residue data are required by July 30, 1986 for carrot, radish, sugar beet.

Residue data are required by July 30, 1986 beans and peas.

Additional data are required by July 30, 1986 to support the established tolerance for soybean hay.

Data are required by July 30, 1986 for pendimethalin and its metabolite in or on soybean hay and straw.

If new metabolites are found, then additional field residue data for field corn may be required. When necessary, data will be extrapolated from the soybean processing study to corn.

If new residue metabolites are found, additional metabolism and field residue data may be required for sorghum.

Additional processing data may be required for cottonseed. When necessary, data will be extrapolated from the requested soybean processing study.

Additional metabolism and processing data on peanuts may be required. When necessary, data will be extrapolated from the soybean processing study.

Additional processing data may be required for sunflower seeds. When necessary, data will be extrapolated from the requested soybean processing study.

Residues of pendimethalin and its metabolite in catfish and crayfish are required by July 30, 1986.

Lactating ruminants must be dosed with pendimethalin to determine residues levels in milk.

A study on metabolites of pendimethalin in poultry will be required if additional metabolites of concern are found in the plant metabolism studies. The need for a poultry feeding study will depend upon the results of a poultry metabolism study.

The following data are required by July 30, 1986 for tobacco: Residue data involving the metabolism of pendimethalin in tobacco. If residues exceed 0.1 ppm, additional data on pyrolysis products must be submitted.

6. Contact Person at EPA:

Robert J.Taylor (703) 557-1800
Office of Pesticide Programs, EPA,
Registration Division (TS-767C)
Fungicide-Herbicide Branch
401 M Street., S.W.
Washington, DC 20460.

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